

EARTHRISE

**Earthrise Nutritionals, Inc.**

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October 8, 2004

Susan J. Walker, M.D., Director,  
Division of Dietary Supplement Programs (HFS-810),  
Center for Food Safety and Applied Nutrition,  
Food and Drug Administration,  
Department of Health & Human Services  
5100 Paint Branch Parkway,  
College Park, MD 20740

OCT 18 2004

**Re: Notification of Structure/Function Statements**

Dear Dr. Walker,

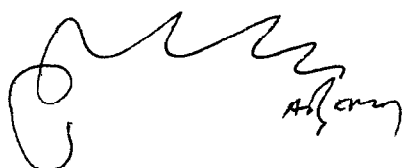
As per 21 CFR section 101.93, this letter is a notification of new structure/function claims to be made on labels, brochures and collateral materials of various Earthrise Nutritionals Spirulina & Spirulina-based dietary supplements.

Manufacturer/Packer/Distributor: Earthrise Nutritionals, Inc.

The structure-function statements are listed on the enclosed attachment. The products include: Earthrise® Spirulina Natural™, Earthrise® Spirulina Organic™, Green Blends Cleansing Formula & Green Blends Light Appetite® Formula.

The firm believes it has substantiation, and the structure-function claims are appropriate, truthful and not misleading. If you have any questions or concerns, please do not hesitate to contact me at (760) 348-5027 extension 21.

Sincerely yours,



Amha Belay, Ph.D.  
Senior Vice President/Scientific Director

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Enclosure

October 8, 2004

**Structure/Function Statements For Earthrise Nutritionals, Inc.**  
**Spirulina & Spirulina-Based Dietary supplements**

**1) Spirulina Natural™ & Spirulina Organic™:**  
(Tablet/capsule/powder)

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**Spirulina Natural™ Ingredient:** Earthrise® Spirulina Natural™  
(*Spirulina (Arthrospira) platensis*).

**Spirulina Organic™ Ingredient:** Earthrise® 100% Certified Organic Spirulina  
(*Spirulina (Arthrospira) platensis*).

**1.1) Longevity & Good Health Structure/Function Statements**

- Promotes longevity.\*
- Enhance longevity.\*
- Green super food for longevity.\*
- Spirulina Natural™ is a green super food for longevity and it provides immune defense and natural antioxidant protection.\*
- Eat your Spirulina greens for good health !\*
- Eating Spirulina greens promotes good health!\*

**1.2) Immune & Antioxidant Structure/Function Statements**

- Immune Defense & Natural Antioxidant Protection.\*

-Earthrise® Spirulina Natural™ (or Spirulina Organic™ ) promotes immune health and provides antioxidant benefits.\*

-Earthrise® Spirulina Natural™ (or Spirulina Organic™ ) promotes immune health and provides antioxidant protection.\*

### **1.3) Immune Structure/Function Statements**

-Strengthen the immune system.\*

-Strengthen your immune system. Studies have shown that Spirulina helps to fortify your body's natural defenses through the immune system.\*

-Studies have shown that phytonutrients, like phycocyanin and polysaccharides from Spirulina modulate the immune system favorably.\*

-The evidence for the immune modulation properties of Spirulina is overwhelming. There are published studies feeding Spirulina to humans, mice, hamsters, chickens, turkeys and cats that show Spirulina regulates the function of the immune system positively by increasing the number and/or activity of some important specialized immune cells.\*

-Athletes often exercise too much, much more than the normal exercise needed to maintain good health. Under such circumstances some imbalance in immune system function can occur. Spirulina may help balance immune system function. Through its function in modulating the immune system, Spirulina may increase energy, endurance and stamina in athletes.\*

-Increases natural killer (NK) cell activity.\*

-Earthrise® Spirulina can stimulate natural killer(NK) cell cytotoxicity & enhances other functional aspects of the immune system.\*

-Earthrise® Spirulina supports immune function by enhancing the activity of natural killer (NK) cells.\*

-Promotes T-cell activity.\*

#### **1.4) Antioxidant Structure/Function Statements**

-Increase antioxidant protection.\*

-Antioxidants help to protect the body from the damaging effects of free radicals.\*

-Increase antioxidant protection. Natural antioxidants in Spirulina clean up excess free radicals and may prevent premature aging.\*

-  $\beta$ -Carotene is a powerful antioxidant- its role in cellular protection is very well established in addition to its regulating the immune system.\*

-Spirulina contains a variety of carotenoids which work in synergy as antioxidants protecting our cells from the damaging effects of free radicals. The two most important carotenoids are a)  $\beta$ -carotene, which is known to promote cellular health and b) zeaxanthin, which is known to promote eye health.\*

#### **1.5) Other Structure/Function Statements**

-Phycocyanin is important because of its antioxidant and anti-inflammatory activities. It may also be important in blood cell regeneration and detoxification.\*

-Reduce the negative effects of the body's normal inflammatory response. Inflammation is the body's first line of defense against foreign attack, but when it goes unchecked, it leads to conditions that promote premature aging. Antioxidants in Spirulina clean up the free radicals that are produced during normal inflammatory response.\*

-Iron deficiency anemia is a very common nutritional disorder in pregnant women. The risk factor during pregnancy is about 25% (250 per 1,000 live births).

Spirulina's content of bioavailable iron, in addition to a balanced iron-rich diet, helps restore this deficiency.\*

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(The disclaimer appears in the appropriate places on labels and brochures).

## **2) Green Blends – Cleansing Formula:** (Caplet/powder)

**Ingredients:** Earthrise® Spirulina, Chlorella, Barley Grass, Wheat Grass, Alfalfa and Broccoli.

-Green food(s) for Cleansing.\*

-Helps to detoxify your body naturally.\*

-Earthrise® Green Blends – Cleansing Formula helps to detoxify your body naturally.\*

-Earthrise® Green Blends – Cleansing Formula contains 6 key green ingredients which help to detoxify your body naturally.\*

-Earthrise® Green Blends – Cleansing Formula is a Spirulina-based green supplement that helps to detoxify your body naturally.\*

-Earthrise® Green Blends – Cleansing Formula - A Spirulina-based green supplement with a meaningful combination of Earthrise® Spirulina, Chlorella, Barley Grass, Wheat Grass, Alfalfa and other natural greens which help to detoxify the body naturally.\*

-Earthrise® Green Blends – Cleansing Formula contains a meaningful combination of Earthrise® Spirulina, Chlorella, Barley Grass, Wheat Grass, Alfalfa and other natural greens for detoxification.\*

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(The disclaimer appears in the appropriate places on labels and brochures).

### 3) **Green Blends – Light Appetite® Formula:** (Caplet)

**Ingredients:** Proprietary Blend (2118 mg): Earthrise® Spirulina, Alfalfa, non-GMO Lecithin, Apple Cider Vinegar, Kelp, Bladderwrack, Plantain, Bromelain, L-Phenylalanine, Pyridoxine HCl, Ascorbic Acid, *Gymnema sylvestre*, Niacin, Chromium Chelate, Thiamine Mononitrate, Riboflavin, and Cyanocobalamin.

-Green food for weight management.\*

-Supports weight maintenance.\*

-Curbs the appetite naturally.\*

-Use this product with a proper diet and adequate exercise for a winning combination to support long-term weight management.\*

-Contains an Earthrise® Spirulina-based, proprietary, unique & natural formula for weight management.\*

-Earthrise® Green Blends – Light Appetite® Formula has a proprietary, unique and natural formula for supporting weight maintenance.\*

-Earthrise® Green Blends – Light Appetite® Formula has a proprietary, unique and natural formula for supporting weight maintenance without stimulants.\*

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-Earthrise® Green Blends – Light Appetite® Formula is a Spirulina-based green supplement with a proprietary, unique and natural formula for supporting weight maintenance.\*

-Earthrise® Green Blends – Light Appetite® Formula - A Spirulina-based green supplement containing a proprietary, unique and natural formula designed to support weight maintenance.\*

-Earthrise® Green Blends – Light Appetite® Formula is a stimulant-free blend of Earthrise® Spirulina, sea vegetables, herbs, minerals and vitamins which work in synergy to curb your appetite naturally.\*

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(The disclaimer appears in the appropriate places on labels and brochures).

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